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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/382,622 08/25/99 DEES

H PHO-107-DIV

EXAMINER

HM22/0913

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GABEL, G	
ART UNIT	PAPER NUMBER

1641

DATE MAILED:

19
09/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/382,622

Applicant(s)

DEES ET AL.

Examiner

Gailene R. Gabel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 14, 15, 18-20, 50-52 and 55-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 14, 15, 18-20, 50-52 and 55-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/8/01 has been entered.

Amendment Entry

2. Applicant's amendment and response filed 7/8/01 in Paper No. 14 is acknowledged and has been entered. Claims 12-13, 16, 23, 25-27, 54, 58, and 59 have cancelled. Claims 1, 4-7, 9-10, 14-15, 18, 51-52, and 55 have been amended. Accordingly, claims 1-10, 14-15, 18-20, 50-52, and 55-57 are pending and under examination.

Rejections Withdrawn

Claim Rejections - 35 USC § 112/103

3. The rejection of claims 15-16, 23, 25-27, and 54 under 35 U.S.C. 112, second paragraph, is now moot in light of Applicant's cancellation of the claims or otherwise withdrawn in light of Applicant's amendment.

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4. The rejection of claims 25-27 under 35 U.S.C. 103(a) as being unpatentable over Serafini et al. (Journal of Nuclear Medicine, 1975) or Neckers D. (Journal of Photochemistry and Photobiology, A: Chemistry 47: 1-29 (1989)) in view of Khaw et al. (US 5,780,052) is now moot in light of Applicant's cancellation of the claims.

Rejections Maintained

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-3, 5-8, and 12-13 stand rejected under 35 U.S.C. 102(b) as being inherently anticipated by Serafini et al. (Journal of Nuclear Medicine, 1975) for reasons of record.

6. Claims 1-3, 5-9, and 12-13 stand rejected under 35 U.S.C. 102(b) as being inherently anticipated by Neckers D. (Journal of Photochemistry and Photobiology, A: Chemistry 47: 1-29 (1989)) for reasons of record.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 4, 14, and 18-20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Serafini et al. (Journal of Nuclear Medicine, 1975) or Neckers D. (Journal of Photochemistry and Photobiology, A: Chemistry 47: 1-29 (1989)) in view of Khaw et al. (US 5,780,052) for reasons of record.

8. Claim 10, 51, 52, and 56-57 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Serafini et al. (Journal of Nuclear Medicine, 1975) or Neckers D. (Journal of Photochemistry and Photobiology, A: Chemistry 47: 1-29 (1989)) in view of Norman et al. (Invest Radiol, 26: S120-S121, 1991) for reason of record.

Response to Arguments

9. Applicant's arguments filed 7/8/01 have been fully considered but they are not persuasive.

A) Applicant argues that the agents in the present invention are "medicinal drugs" that can be administered to patients, i.e. medicinal purposes, to improve efficacy of radiation therapy. Specifically, Applicant contends that the existing reagent grade commercial product, i.e. reagent grade Rose Bengal, used in industrial laboratory is completely distinct from the claimed drug product for use in radiation therapy, specifically used as a radiosensitizer for treatment of cancers and tumors comprising halogenated xanthene which interacts with ionizing radiation applied to said cancer or tumor.

In response, the discovery of a new property of a known product, in this case, Rose Bengal as a radiosensitizer, does not render the product novel; unless otherwise, rendered novel or nonobvious from modification or variation therefrom, i.e. "ionized Rose Bengal" or "non-radioactive Rose Bengal" or "pharmaceutical Rose Bengal" that is structurally different, novel, and nonobvious, i.e. with different pH (as an example) from all other commercially known Rose Bengal.

B) Applicant argues that the claims are directed to novel and nonobvious combinations of 1) radiosensitizer agent comprising a halogenated xanthene, 2) interacting with ionizing radiation applied to a cancer or tumor, 3) to enhance therapeutic efficiency of the ionizing radiation. Applicant argues that none of the cited references disclose or suggest that a halogenated xanthene or Rose Bengal is a radiosensitizer or radiosensitizer agent for use with ionizing radiation. Specifically, Serafini et al. disclose Rose Bengal and a use thereof but fails to disclose Applicant's

specific "radiosensitizer combination" aforementioned. Therefore, Rose Bengal sold for "use" for diagnostic purposes in Serafini et al. would have a different label as a different drug, i.e. commercial entity. Applicant also contends that Serafini et al. does not teach or suggest the agent of the claimed invention as a radiosensitizer agent for use with radiosensitization or ionizing radiation in the treatment of cancer or tumors. Specifically, Applicant argues that Serafini et al.'s use of Rose Bengal is completely different from the radiosensitizer agent of claim 1.

In response, Examiner concurs that Serafini et al. does not disclose **use** of Rose Bengal as a radiosensitizer agent for use with ionizing radiation to treat cancer or tumor. Examiner concurs that Serafini et al.'s **use** is completely different from **use** as the radiosensitizer agent of claim 1. Applicant, however, does not appear to claim the **use** of Rose Bengal as radiosensitizer agent but appears to claim Rose Bengal as the radiosensitizer agent, or otherwise, Rose Bengal as the product itself, in combined use with ionizing radiation; thus a radiosensitizer agent. Serafini et al. teach a different **use** of Rose Bengal but, nevertheless, use the same Rose Bengal having the same structure and functional properties as the radiosensitizer agent recited in claim 1. Therefore, absent any evidentiary showing that the structure of the Rose Bengal taught by Serafini et al. distinctly differs from the claimed invention, absent evidentiary showing that the Rose Bengal as taught by Serafini et al. would not have exhibited the same (inherent) property as a radiosensitizing agent upon exposure to ionizing radiation, it is maintained that the Rose Bengal taught by Serafini et al. is the same compound as the radiosensitizer agent taught in the claimed invention. As an example, an "ionized Rose

Bengal" or "non-radioactive Rose Bengal" that is structurally different, novel, and nonobvious, i.e. with different pH (as an example) from all other commercially known Rose Bengal.

C) Applicant argues that Neckers does not teach or suggest the agent of the claimed invention as a radiosensitizer agent for use with radiosensitization or ionizing radiation in the treatment of cancer or tumors. Applicant argues that Necker's teaching of use in optical radiation of Rose Bengal is completely different from the use with ionizing radiation as radiosensitizer agent of claim 1.

In response, Examiner concurs that Neckers does not disclose **use** of Rose Bengal as a radiosensitizer agent for use with ionizing radiation to treat cancer or tumor. Examiner concurs that Necker's **use** is completely different from use as the radiosensitizer agent of claim 1. Applicant, however, does not appear to claim the **use** of Rose Bengal as radiosensitizer agent but appears to claim Rose Bengal as the radiosensitizer agent, or otherwise, Rose Bengal as the product itself, in combined use with ionizing radiation; thus a radiosensitizer agent. Neckers teaches a different **use** of Rose Bengal but, nevertheless, teaches the same Rose Bengal having the same structure and functional properties as the radiosensitizer agent recited in claim 1. Therefore, absent any evidentiary showing that the structure of the Rose Bengal taught by Neckers distinctly differs from the claimed invention, absent evidentiary showing that the Rose Bengal as taught by Neckers would not have exhibited the same (inherent) property as a radiosensitizing agent upon exposure to ionizing radiation, it is maintained

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that the Rose Bengal taught by Serafini et al. is the same compound as the radiosensitizer agent taught in the claimed invention. As an example, an "ionized Rose Bengal" or "non-radioactive Rose Bengal" that is structurally different, novel, and nonobvious, i.e. with different pH (as an example) from all other commercially known Rose Bengal.

D) Applicant argues that the combination of Serafini et al. or Neckers with Khaw et al. does not teach or suggest the agent of the claimed invention as a radiosensitizer agent for use with radiosensitization or ionizing radiation in the treatment of cancer or tumors. Applicant argues that Khaw et al. does not correct the deficiencies of Serafini et al. and Neckers. Specifically Khaw et al. does not suggest **use** of halogenated xanthene as radiosensitizer agent such as recited in claim 1.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, Examiner concurs that Serafini et al. or Neckers combined with Khaw et al. do not suggest **use** of Rose Bengal as a radiosensitizer agent for use with ionizing radiation to treat cancer or tumor. Examiner concurs that **use** of the combined references is completely different from the **use** of the radiosensitizer agent of the rejected claims. However, the combined references, nevertheless, suggest the same Rose Bengal having the same structure and functional properties as the radiosensitizer

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agent recited in the rejected claims. Therefore, absent any evidentiary showing that the structure of the Rose Bengal suggested by the combined references distinctly differs from the claimed invention, absent evidentiary showing that the Rose Bengal as suggested by the same references would not have exhibited the same (inherent) property as a radiosensitizing agent upon exposure to ionizing radiation, it is maintained that the Rose Bengal suggested by the combined references is the same compound as the radiosensitizer agent taught in the claimed invention. As an example, an "ionized Rose Bengal" or "non-radioactive Rose Bengal" that is structurally different, novel, and nonobvious, i.e. with different pH (as an example) from all other commercially known Rose Bengal.

E) Applicant argues that the combination of Serafini et al. or Neckers with Norman does not teach or suggest the agent of the claimed invention as a radiosensitizer agent for use with radiosensitization or ionizing radiation in the treatment of cancer or tumors. Applicant argues that Norman does not correct the deficiencies of Serafini et al. and Neckers. Specifically Norman does not suggest **use** of halogenated xanthene as radiosensitizer agent such as recited in claim 1.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this case, Examiner concurs that Serafini et al. or Neckers combined with Norman do

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not disclose **use** of Rose Bengal as a radiosensitizer agent for use with ionizing radiation to treat cancer or tumor. Examiner concurs that **use** of the combined references is completely different from the **use** of the radiosensitizer agent of the rejected claims. However, the combined references, nevertheless, suggests the same Rose Bengal having the same structure and functional properties as the radiosensitizer agent recited in the rejected claims. Therefore, absent any evidentiary showing that the structure of the Rose Bengal suggested by the combined references distinctly differs from the claimed invention, absent evidentiary showing that the Rose Bengal as suggested by the same references would not have exhibited the same (inherent) property as a radiosensitizing agent upon exposure to ionizing radiation, it is maintained that the Rose Bengal suggested by the combined references is the same compound as the radiosensitizer agent taught in the claimed invention. As an example, an "ionized Rose Bengal" or "non-radioactive Rose Bengal" that is structurally different, novel, and nonobvious, i.e. with different pH (as an example) from all other commercially known Rose Bengal.

10. No claims are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gail Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday to Thursday from 7:00 AM to 4:30 PM. The examiner can also be reached on alternate Fridays from 7:00 AM to 3:30 PM.

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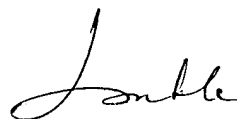
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 308-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Gail Gabel
Patent Examiner
Group 1641

9/10/01



LONG V. LE
SUPERVISORY PATENT EXAMINER
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09/10/01